DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 19-219/S-019
NDA 19-814/S-011

Allergan, Inc.
Attention: Lewis Gryziewicz
Director, Regulatory Affairs
2525 Dupont Drive
P.O. Box 19534
Irvine, CA 92623-9534

Dear Mr. Gryziewicz:

Please refer to your supplemental new drug applications dated November 1, 2000, received November 2, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Betagan (levobunolol hydrochloride ophthalmic solution, USP) 0.25% and 0.5%.

We acknowledge receipt of your March 30, 2001, submission to each supplemental application.

These supplemental new drug applications provide revised draft labeling of the package insert.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling of the package insert submitted March 30, 2001. However, the following additions to the package insert are recommended:

1. The pH and osmolality should be specified in the Description section.

2. The How Supplied section should include the target fill volume for each container size and the color and type of plastic for the bottle, dropper tip, and cap. For example, the product is supplied as “a 5 mL solution in a 7.5 mL opaque white, low density polyethylene bottle with a natural low density polyethylene dropper tip and a yellow polypropylene cap.”

Please submit the copies of final printed labeling (FPL) electronically to each application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplements NDA 19-219/S-019 and NDA 19-814/S-011." Approval of these submissions by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to these NDAs and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

Please submit one market package of the drug product when it is available.

We remind you that you must comply with the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, call Michael Puglisi, Project Manager, at (301) 827-2090.

Sincerely,

{See appended electronic signature page}

Wiley A. Chambers, M.D.
Deputy Director
Division of Anti-Inflammatory, Analgesic and Ophthalmic
Drug Products, HFD-550
Office of Drug Evaluation V
Center for Drug Evaluation and Research